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OCTOBER TERM, 1977

LUTRELLE F. PARKER, ACTING COMMISSIONER OF
PATENTS AND TRADEMARKS, PETITIONER

v.

MALCOLM E. BERGY, ET AL.

PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

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**PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS**

The Solicitor General, on behalf of the Acting Commissioner of Patents and Trademarks, petitions for a writ of certiorari to review the judgment of the United States Court of Customs and Patent Appeals in this case.

OPINIONS BELOW

The opinion of the Court of Customs and Patent Appeals (App. A, *infra*, 1a-29a) is reported at 563 F.2d 1031. The opinion of the Patent and Trademark

Office Board of Appeals (App. C, *infra*, 31a-44a) is reported at 197 U.S.P.Q. 78. The opinion of the patent examiner (App. D, *infra*, 45a-46a) is not reported.

JURISDICTION

The judgment of the Court of Customs and Patent Appeals was entered on October 6, 1977, and rehearing was denied on November 23, 1977 (App. B, *infra*, 30a). On February 14, 1978, Mr. Justice Brennan extended the time to file a petition for a writ of certiorari to and including April 22, 1978. The jurisdiction of this Court is invoked under 28 U.S.C. 1256. *Gottschalk v. Benson*, 409 U.S. 63; *Dann v. Johnston*, 425 U.S. 219.

QUESTION PRESENTED

Whether a living organism is patentable subject matter under 35 U.S.C. 101.

STATUTES INVOLVED

35 U.S.C. 101 provides:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The Plant Patent Act of 1930, as amended, 35 U.S.C. 161, provides in relevant part:

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor * * *.

Section 42(a) of the Plant Variety Protection Act of 1970, 84 Stat. 1547, 7 U.S.C. 2402(a), provides in relevant part:

The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety, or his successor in interest, shall be entitled to plant variety protection therefor * * *.

STATEMENT

On June 10, 1974, Malcolm E. Bergy and two other scientists filed a patent application (R. 6-27), assigned to the Upjohn Company,¹ with four claims to a process for preparing the antibiotic lincomycin using a newly isolated bacterium, *Streptomyces vellosus* ("S. vellosus") (App. A, *infra*, 1a-2a).² This bacterium was found in Arizona soil samples (R. 11). Claims 1-4 described the process of cultivating *S. vellosus* in a nutrient medium at prescribed tempera-

¹ Brief for the Appellants, *In re Application of Malcolm E. Bergy, et al.*, C.C.P.A., No. 76-712, p. 2.

² A subculture of *S. vellosus*, supplied by Upjohn, is permanently maintained by the Department of Agriculture at its research facilities. It is identified by its accession number, NRRL 8037 (App. A, *infra*, 3a).

tures to produce lincomycin, a previously known antibiotic (App. A, *infra*, 1a-2a). By amendment, the applicants added a fifth claim for a culture of *S. vellosus* itself, as follows (App. C, *infra*, 31a):

A biologically pure culture of the microorganism *Streptomyces vellosus*, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances.

The examiner allowed claims 1-4, and his decision on those claims is not in dispute (App. D, *infra*, 45a). He rejected claim 5 on the basis that *S. vellosus* was a product of nature and thus not patentable (*ibid.*). A request for reconsideration was denied on the same ground (App. D, *infra*, 46a).

The Board of Appeals, with one member dissenting, sustained the rejection of claim 5 on the ground that a living organism is not patentable subject matter under 35 U.S.C. 101 (App. C, *infra*, 31a-44a). The Board found support for this view in the Plant Patent Act of 1930, as amended, 35 U.S.C. 161 *et seq.* It reasoned that Congress would not have specifically given patent protection under the 1930 Act to certain kinds of plants if Congress had believed that patents could already be obtained for these plants, as living organisms, under R.S. 4886, now 35 U.S.C. 101 (App. C, *infra*, 33a). The Board noted that the proponents of this legislation stated that it would for the first time

extend patent protection to plant breeders (*ibid.*). The Board did not reach the "product of nature" issue upon which the examiner's decision rested.³

The Court of Customs and Patent Appeals reversed, with two judges dissenting (App. A, *infra*, 1a-29a). The court recognized that the question whether a microorganism is patentable subject matter was one of first impression (App. A, *infra*, 11a). The majority noted that microorganisms have come to be important tools in the chemical industry and that they act in the same way as inanimate chemical compositions such as reactants and catalysts (App. A, *infra*, 18a-19a). The court reasoned that, since patents are available for processes using a strain of living bacteria (*e.g.*, in septic systems or to produce alcohol), it would be "illogical" to insist that the living bacteria in a biologically pure culture are not themselves statutory subject matter (App. A, *infra*, 16a).⁴

Judge Miller, dissenting in an opinion in which Judge Baldwin joined, agreed with the Board's analysis of the legislative history, and concluded that there

³ The dissenting Board member concluded that claim 5 involved a "composition" or "manufacture" and was accordingly patentable under 35 U.S.C. 101 (App. C, *infra*, 35a-44a).

⁴ While Judge Rich and Chief Judge Markey concluded that the "product of nature" issue was not before the court, they stated that a biologically-pure culture of bacteria, produced by isolating it from its natural surroundings under carefully controlled laboratory conditions, is man-made, rather than a product of nature (App. A, *infra*, 9a-10a). Judge Kashiwa, concurring, expressed no opinion on this issue (App. A, *infra*, 21a).

were legally significant differences both between an inanimate chemical reagent and a living organism and between a process using a microorganism and the microorganism itself (App. A, *infra*, 22a-29a).⁶

REASONS FOR GRANTING THE WRIT

In concluding that living things are patentable subject matter under 35 U.S.C. 101, the Court of Customs and Patent Appeals has significantly extended the scope of the patent laws, and thus erroneously exercised the legislative prerogative.

1. The decision below is the first holding by any court that living things are themselves patentable; dicta in earlier cases suggested that they were not. See, e.g., *Guaranty Trust Co. v. Union Solvents Corp.*, 54 F. 2d 400, 410 (D. Del.), affirmed, 61 F. 2d 1041 (C.A. 3), certiorari denied, 288 U.S. 614; *Application of Mancy, et al.*, 499 F. 2d 1289, 1294 (C.C.P.A.)

The economic implications of this conclusion, as the court below itself recognized (App. A, *infra*, 18a-19a), are significant. Since the number of living things is vast, the decision opens an enormous range of subject matter to patentability. Although the court below attempted to restrict its holding to microorganisms (App. A, *infra*, 11a, 18a, 20a), microorganisms and other basic life forms are perhaps the most

⁶ The dissenting judges also concluded that the "product of nature" issue was not before them, and expressed no opinion on it (App. A, *infra*, 29a).

important areas of research in the life sciences.⁶ Therefore, unless the instant decision is reversed, the policy problems of genetic engineering, already highly controversial,⁷ will be further complicated by crystallized patent considerations.⁸

As this Court stressed in *Gottschalk v. Benson*, 409 U.S. 63, 72-73, policy decisions concerning the extension of the patent laws to new fields are for Congress, not the courts. Accordingly, where new technologies are involved it is particularly important for the

⁶ Moreover, the nature of living things—especially microorganisms—creates a serious risk that a patent monopoly will exceed its lawful limits. The difficulty of describing and understanding microorganisms creates serious problems in determining whether competitive developments are lawful or infringing. Cf. *Yoder Bros., Inc. v. California-Florida Plant Corp.*, 537 F. 2d 1347, 1379-1383 (C.A. 5), certiorari denied, 429 U.S. 1094; Jeffery, *The Patentability and Infringement of Sport Varieties: Chaos or Clarity?*, 59 J. Pat. Off. Soc'y 645, 654-657 (1977).

⁷ See "Guidelines for Research Involving Recombinant DNA Molecules," released by the National Institutes of Health, 41 Fed. Reg. 27902-27943 (July 7, 1976). See also "Recombinant DNA: Accelerated Processing of Patent Applications for Inventions," 42 Fed. Reg. 2712-2713 (January 13, 1977), suspended in part by "Recombinant DNA: Suspension of Accelerated Processing of Patent Applications for Recombinant DNA Research Inventions," 42 Fed. Reg. 13147 (March 9, 1977).

⁸ Indeed, the Court of Customs and Patent Appeals relied on the instant decision in recently reversing the Appeal Board's denial of patentability to a genetically engineered microorganism. *In re Chakrabarty*, C.C.P.A., No. 77-535, decided March 2, 1978, 197 U.S.P.Q. 72. We are considering whether to seek review of that decision.

courts to interpret the patent laws so that "the prerequisites to obtaining a patent are strictly observed." *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230.⁹ But the court below relied upon its own views of what would constitute a logical or desirable patent policy,¹⁰ rather than carefully analyzing the policies adopted by Congress in the relevant statutes.

2. Such an analysis strongly suggests that Congress did not intend the categories of patentable subject matter described in Section 101 to include living things. Instead, when it believed that it was appropriate to extend patent protection to particular types of living things, it developed special statutory provisions to do so, and imposed the particular requirements it considered appropriate in the circumstances.

In 1930, Congress enacted the Plant Patent Act, 35 U.S.C. 161 *et seq.*, to afford patent protection to certain kinds of asexually-reproduced plants. Congress evidently believed that existing patent law did not extend to living things; if plants, as living things, already were patentable under Section 101, there would have been no need to provide specifically for

⁹ In *Stiffel*, this Court held that even a State's concern with unfair competition could not prevail over the exclusive responsibility of Congress to determine the extent of the patent laws.

¹⁰ See, e.g., App. A, *infra*, 16a, 19a-20a. In any event, the court's conclusion that it would be illogical to allow patents on processes that use living bacteria, but not on the bacteria themselves, is incorrect. Cf. the government's brief in *Parker v. Flook*, No. 77-642, filed March 3, 1978, pp. 19-23.

plant patents. The legislative history of the 1930 Act confirms that Congress intended for the first time to extend patent protection beyond its previous limits. Both the House and Senate committees considering the bill reported that:

The purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry * * *. The bill will remove the existing discrimination between plant developers and industrial inventors. [H.R. Rep. No. 1129, 71st Cong., 2d Sess. 1 (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 1 (1930).]¹¹

Forty years later, Congress again evidenced its belief that living organisms were not covered by 35 U.S.C. 101, and that to afford them protection separate legislation was needed. The Plant Variety Protection Act of 1970, 84 Stat. 1542, 7 U.S.C. 2321 *et seq.*, gave the Secretary of Agriculture authority to issue certificates of Plant Variety Protection, similar to patents, for new varieties of sexually-reproduced plants (Section 51 of the Act, 7 U.S.C. 2421). Signifi-

¹¹ Appended to both the House and Senate Reports were letters from then Secretary of Agriculture Hyde, referring more specifically to the coverage of the pre-existing patent law:

The evident purpose of the bill is to encourage the improvement of some kinds of cultivated plants * * *. This purpose is sought to be accomplished by bringing the reproduction of such newly bred or found plants under the patent laws which at the present time are understood to cover only inventions or discoveries in the field of inanimate nature. [H.R. Rep. No. 1129, 71st Cong., 2d Sess. 10 (Appendix A) (1930); S. Rep. No. 315, 71st Cong., 2d Sess. 9 (Appendix A) (1930).]

cantly, the statute expressly provides that bacteria are not entitled to protection (Section 42, 7 U.S.C. 2402).

Again, the legislative history of the Act unmistakably indicates that Congress was extending protection to materials not previously covered under the patent laws—*i.e.*, materials that were not within the terms of either the 1930 Act or 35 U.S.C. 101. Thus, the House Report states (H.R. Rep. No. 91-1605, 91st Cong., 2d Sess. 1 (1970)):

Under patent law, protection is presently limited to those varieties of plants which reproduce asexually * * *. No protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. Thus, patent protection is not available with respect to new varieties of most of the economically important agricultural crops, such as cotton or soybeans.

The court below dismissed this legislative history with the terse comment (App. A, *infra*, 20a):

Nor are we influenced by the legislative history of the Plant Patent Act of 1930 in the course of which nobody had anything to say about patent protection for microorganisms, so far as we know. The collective mind of Congress was not turned in that direction.

If the court meant that plants have always been patentable under Section 101 and its predecessors, its statement is squarely at odds with the sense and the legislative history of the Plant Patent and Plant Variety Protection Acts. If, on the other hand, it

meant that under Section 101 certain kinds of living things—plants—were not patentable subject matter until the passage of the 1930 Act, but that microorganisms are not plants, and had always been patentable, it has created an untenable distinction among living things, a distinction that finds no support in Section 101. Moreover, that distinction would seem to be contrary to the court's own precedent. In *In re Arzberger*, 112 F. 2d 834, 837 (C.C.P.A.), the court recognized that "the characteristics of plants predominate in bacteria, and bacteria are usually scientifically classified as plants."¹² And Congress evidently shared that view, for in the 1970 Plant Variety Protection Act it took pains specifically to exclude bacteria from the coverage of the statute, thus apparently assuming that bacteria are plants. See 7 U.S.C. 2402(a).

¹² The court nevertheless affirmed the Board's refusal to issue a plant patent for certain bacteria. Nothing in *Arzberger* implies that the bacteria could have been patented under the general patent law. Instead, the court quoted with approval the examiner's statement that the Plant Patent Act was not designed "to afford patent protection for bacteria used in the production of butyl alcohol, ethyl alcohol, and acetone" (112 F. 2d at 836), suggesting that no such protection was otherwise available.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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APRIL 1978.

APPENDIX A

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

Patent Appeal No. 76-712
IN THE MATTER OF THE APPLICATION

of

MALCOLM E. BERGY, JOHN H. COATS, and
VEDPAL S. MALIK

Serial No. 477,766

DECIDED: OCTOBER 6, 1977

RICH, Judge.

This appeal is from the majority decision of the divided Board of Appeals (board) of the United States Patent and Trademark Office (PTO) affirming the rejection of claim 5 of application serial No. 477,766, filed June 10, 1974. We reverse.

The Invention

The subject of the application, which, when filed, had the noncommittal title "Process," is made clear from the Abstract of the Disclosure, which reads:

Microbiological process for preparing the antibiotic lincomycin at temperatures ranging from 18° C. to 45° C. using the newly discovered

microorganism *Streptomyces vellosus*. The subject process advantageously results in the preparation of lincomycin without the concomitant production of lincomycin B (4'-depropyl-4'-ethyl-lincomycin). The absence of lincomycin B production results in increased lincomycin recovery efficiency.

On demand of the examiner, the title was later changed to "Process for Preparing Lincomycin." The application was filed with four claims to such a process which the examiner allowed. By a preliminary amendment, filed before any action on the application but not reached by the examiner until his second action, claim 5 was added together with the attorney's statement that "Basis for claim 5 can be found throughout the disclosure." That claim reads:

5. A biologically pure culture of the microorganism *Streptomyces vellosus*, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances.

The designation "NRRL 8037" in claim 5 is elucidated by the following statement in the specification:

The Microorganism

The novel actinomycete used according to this invention for the production of lincomycin is *Streptomyces vellosus*. One of its strain characteristics is the production of lincomycin without

the concomitant production of lincomycin B. Another of its strain characteristics is the production of comparable titers of lincomycin at a temperature of 28° C. and 45° C. A subculture of this living organism can be obtained upon request from the permanent collection of the Northern Regional Research Laboratories, Agricultural Research Services, U.S. Department of Agriculture, Peoria, Illinois, U.S.A. Its accession number in this repository is NRRL 8037.

The specification continues:

The microorganism of this invention was studied and characterized by Alma Dietz of the Upjohn Research Laboratory.

What follows that statement is an elaborate, highly technical, detailed description of the microorganism, including its type designation as "*Streptomyces vellosus* Dietz, sp.n.," occupying over ten pages of the printed specification, followed by exemplary descriptions of the production of lincomycin therefrom by fermentation processes and the recovery of the lincomycin produced by the fermentation.

The Rejection

No references have been cited against claim 5 because the novelty and unobviousness of the biologically pure culture claimed are not questioned. Neither has utility been questioned.

The examiner's sole ground of rejection of claim 5, as stated in his final rejection, was:

Claim 5 is rejected under 35 USC 101 as non-statutory subject matter. Claim 5 claims a product of nature (*Streptomyces vellosus* NRRL 8037). See *In re Mancy et al.* 182 USPQ 303 at page 306, second sentence before [4].

Appellants responded with a request to reconsider this rejection supported by affidavits of three Upjohn microbiologists, Dr. Joseph E. Grady, Dr. Thomas L. Miller, and "the well-known microbial taxonomist Alma Dietz," pointing out that the microorganism did not exist as a biologically pure culture in nature and asserting that such a culture is a "manufacture" under § 101, which reads:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

In so arguing, appellants made the point that the pure culture is "a product of a microbiologist." The examiner adhered to his position and appeal was taken to the board.

Since the only ground given by the examiner in support of his nonstatutory-subject-matter rejection was that the culture was a product of nature, that was the only point argued by appellants in their brief before the board, in which they cited a number of precedents for holding that a *pure* product could be patentable over a known impure product of similar kind.

The Examiner's Answer—only two pages of the printed record—merely summarized his product-of-nature position and cited two cases in addition to *In re Mancy*, supra, previously cited by him, namely, *Guaranty Trust Co. of New York v. Union Solvents Corp.*, 54 F.2d 400, 12 USPQ 47 (D. Del. 1931), *aff'd*, 61 F.2d 1041, 15 USPQ 237 (CA 3 1932), and *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948). With reference to the cases cited by appellants as precedents for patenting *pure* materials, the examiner noted that they were all pure chemical compounds "as contrasted with the instant microorganism." He noted that the cases cited by him all "involve isolated or biologically pure microorganisms." Appellants replied briefly, taking exception to the last-quoted statement of the examiner

* * * since (1) none of the decisions cited, nor any known decision, has held that a "biologically pure culture" is unpatentable, and (2) there is no evidence that a "biologically pure culture" was in issue in any of the cited decisions.

On the issue thus framed, the case went to the board.

The Board Opinions

The opinion of the majority of the board is quite out of the ordinary. While it affirms the "decision" of the examiner, that is to say his *rejection* of claim 5, it wholly disregards his *reason* for rejecting it to the point of expressly declining to consider it. Instead, the board majority decided that claim 5 is not

directed to statutory subject matter within the meaning of § 101 because it is for "a living organism," an issue entirely new to the application at bar, so far as the record shows. The dissenting board member's opinion confirms in its first paragraph that that is, strictly, the basis of the majority's decision. Without stating a new ground of rejection was being made (*cf.* 37 CFR 1.196(b)), the majority opinion commences its explanation of its reasoning as follows:

We have extensively researched prior court decisions for guidance to the question of whether or not a microorganism, being a living thing, is or is not within the realm of statutory patentable subject matter, but, other than possibly non-controlling dicta, have not found any case directly in point.

It is our view that 35 U.S.C. 101 must be strictly construed and, when so interpreted, precludes the patenting of a living organism. We reach this conclusion on the basis that only those categories of subject matter specifically enumerated in the statute are patentable and a living organism does not fall within the scope of any of those categories listed. An analogous result has been reached by the courts with respect to non-patentability of mental processes, printed matter or methods of doing business none of which are also expressly excluded by the indicated section of the statute, but neither can they be said or have been held to be included thereby.

The board majority opinion then makes two points in support of its conclusion that § 101 precludes pat-

enting anything living. The first is based on this court's decision in *In re Arzberger*, 27 CCPA 1315, 112 F.2d 834, 46 USPQ 32 (1940), that bacteria are not included in the plant patent provision of former Title 35 (then part of § 4886 of the Revised Statutes, since 1952 separately treated in 35 USC 161-164), notwithstanding that they may be scientifically classified as plants, because Congress plainly did not intend them to be when, in 1930, it enacted the Plant Patent Act (46 Stat. 376). The case was concerned only with the plant patent statute and this court did not have before it any other issue, such as inclusion of bacteria in any other statutory category, appellant having applied for a "plant patent" on a bacterium. The second aspect of the board majority's supporting reasoning is fully stated in the following paragraph:

If we were to adopt a liberal interpretation of 35 U.S.C. 101 new types of insects, such as honeybees, or new varieties of animals produced by selective breeding and cross-breeding would be patentable. Moreover, those plants which are excluded from the scope of 35 U.S.C. 161, such as tuber propagated plants or plants which can be reproduced only sexually, would be patentable under 35 U.S.C. 101. We do not believe that Congress intended 35 U.S.C. 101 to encompass any living organism, whether they be plants or microorganisms.

The dissenting board member, stating that he had reviewed all of the precedents cited by either side and others as well, many of which he discussed in detail, expressed these views:

* * * I do not believe that the fact that plants and bacteria have some properties in common is sufficient basis for holding that bacteria are to be excluded from patent coverage. * * *

* * * I do not find it improper to claim living organisms * * *.

In view of the discussed cases, and since 35 U.S.C. 101 does not expressly exclude patents to living organisms, it is my opinion that living organisms, as claimed, may be patented if such claims also fulfill the other requirements of the statute.

He also expressed disagreement with the examiner's view that claim 5 defined a "product of nature," or that being a product of nature was sufficient reason, alone, for holding an invention nonstatutory. He made these observations:

Rather, I view a "product of nature" as being something that "exists" in nature and therefore evidence that it may not be "new" as this expression finds meaning in the Patent Statute. Accordingly, I would treat "products of nature" like any other material and determine whether they are new or obvious in view of the state of the art.

Certainly vitamin B-12, as it exists in liver, and adrenalin, as it appears in adrenal glands, are products of nature, yet the courts have held (*Merck & Co.*, B-12 and *Parke Davis and Co.*, adrenalin)¹ that when such materials are ex-

¹ *Merck & Co. v. Chase Chemical Co.*, 273 F. Supp. 68, 155 USPQ 139 (D. N.J. 1967); *Merck & Co. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156, 116 USPQ 484 (CA 4 1958);

tracted and concentrated in a purified form they are patentable. Accordingly, it is not sufficient to determine whether the pure culture claimed is a product of nature.

OPINION

Under the peculiar circumstances of this case, in which the board switched the supporting reasoning for the rejection of claim 5 as for nonstatutory subject matter without expressly making a new rejection, we deem it prudent to clarify the issue we have to decide. The brief of the PTO Solicitor sees but a single issue: "whether *living* organisms are the kind of 'manufacture' or 'composition of matter' intended by Congress to be included within 35 U.S.C. 101." (Emphasis ours.) Appellants argue that issue, making no objection to the board having raised it sua sponte, and also—perhaps out of an abundance of caution—argue the product-of-nature question sidetracked by the board. Appellants forcefully presented the latter issue before the board and submitted affidavits of three experts in the field to the effect that the "biologically pure culture" of claim 5 is not found in nature. The evidence appears to us to be incontrovertible. The dissenting member of the board accepted it. The board did not refute it, and the solicitor has not challenged it. The circumstances persuade us that the board went in search of another reason to support the rejection because it re-

Parke Davis & Co. v. H. K. Mulford Co., 189 Fed. 95 (S.D. N.Y. 1911), *aff'd*, 196 Fed. 496 (CA 2 1912).

alized the examiner's position was untenable. We consider the product-of-nature issue to have been abandoned and no longer in the case. However, since the solicitor indicated at oral argument that he was not sure the board had removed it entirely, we state that we find it wholly lacking in merit. The biologically pure culture of claim 5 clearly does not exist in, is not found in, and is not a product of, "nature." It is man-made and can be produced only under carefully controlled laboratory conditions.

We take note of the fact that, since their appearance before the board, appellants have added another statutory category string to their bow. Before the board, they argued that the claim 5 pure culture is a "manufacture" under § 101. Before us they also argue that it is a "composition of matter," which is another § 101 category. This is not a matter of great moment since there is considerable overlap between these two broad categories, notwithstanding what some textwriters have said. The arguments have not made a distinction between the two. If it is either, it is statutory subject matter, and it is not intellectually profitable to attempt a distinction in this regard.

We therefore proceed to a decision solely on the basis of the issue as the solicitor has stated it, deeming it to involve the single question of whether the uncontroverted fact that the biologically pure culture, *as claimed*, is *alive* removes it from the categories of inventions enumerated in § 101. Our conclusion is that it does not.

As to what the issue is, however, we make one further clarifying observation. We do so in part because of the solicitor's statement that a similar issue was present but not decided in *In re Merat*, 519 F.2d 1390, 186 USPQ 471 (CCPA 1975), a case involving chicken breeding, and in part because of the board's reasoning herein. The solicitor's statement about *Merat* is correct, but we emphasize that we are not here deciding the issue left open in *Merat* or anything other than the issue before us in this case, whether the subject matter of claim 5 is within either of the terms "manufacture" or "composition of matter" in § 101. In other words, we are not deciding whether living things in general, or, at most, whether any living things other than microorganisms, are within § 101. These questions must be decided on a case-by-case basis and anything said herein is to be taken as said in the context of a discussion of the subject matter of claim 5 and § 101.

As presented to us, the question is clearly one of first impression. There is a substantial volume of literature bearing on it, both directly and indirectly, which the solicitor has helpfully collected in his brief, containing some private views on the question on which, it seems to be agreed, no court has passed.

One of the peripheral court comments, the first to be cited, is from our opinion in *In re Mancy*, 499 F.2d 1289, 182 USPQ 303 (CCPA 1974). All that the case has been cited for is a bit of dictum bearing on a hypothetical situation which was not before us. The case involved claims to a *process* of producing

a particular known antibiotic by aerobically cultivating a particular strain of *Streptomyces bifurcus*. The claims were rejected for obviousness under 35 USC 103 on references showing various strains of other *Streptomyces* species used for the same purpose. We reversed, holding that *In re Kuehl*, 475 F.2d 658, 177 USPQ 250 (CCPA 1973), was controlling and that the new *Streptomyces bifurcus* strain discovered by Mancy himself as part of the invention being claimed could not be used as prior art in determining the obviousness under § 103 of his claims to a process of using it to produce the old antibiotic. In comparing the facts of the case before us in *Mancy* with the facts of *Kuehl*, we said (499 F.2d at 1294, 182 USPQ at 306):

We recognize the differences between this case and the situation in *Kuehl*, where the novel zeolite used as a catalyst in the claimed hydrocarbon cracking processes was itself the subject of allowed claims in the application. Here appellants not only have no allowed claim to the novel strain of *Streptomyces* used in their process but would, we assume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a "product of nature." However, it is not required for unobviousness of the method-of-use claims that the new starting material be patentable
* * *

If it is not clear from the context that we were not discussing what is or is not statutory subject matter

within § 101 but only a difference between two cases which we found not to be a reason for distinguishing them, and that we were not expressing any view, even by way of dictum, on the patentability of living organisms as such, we now make it explicit that the thought underlying our presumption that Mancy could not have obtained a claim to the strain of microorganism he had described was simply that it *lacked novelty*. We were thinking of something pre-existing and merely plucked from the earth and claimed as such, a far cry from a biologically pure culture produced by great labor in a laboratory and so claimed. The dissenting board member was entirely correct in so interpreting our *Mancy* dictum. The examiner relied on it only to support his product-of-nature reasoning, and the board majority did not mention it, having abandoned that reasoning. Furthermore, it now appears to us, in light of what we have learned in this case about the separation and identification of new strains of *Streptomyces*, that our dictum was ill-considered. Had we known what we now know, we would likely have abjured the stated presumption.

Guaranty Trust Co. v. Union Solvents Corp., supra, was cited by the examiner as "especially pertinent" and again by the solicitor as a "judicial precedent" solely for the following passage appearing at the very end of the long trial court opinion (54 F.2d at 410, 12 USPQ at 57, emphasis ours):

Lastly, the defendant contends that the invention of the Weizmann patent is unpatentable

since it is for the *life process* of a living organism. *Were the patent for bacteria per se, a different situation would be presented.* As before stated, the patent is *not* for bacteria *per se*. It is for a fermentation *process* employing bacteria discovered by Weizmann under conditions set forth in the specification and claims. *Undoubtedly there is patentable subject-matter in the invention.* Cochrane v. Deener, 94 U.S. 780, 24 L.Ed. 139; Risdon Iron & Locomotive Works v. Medart, 158 U.S. 68, 15 S. Ct. 745, 39 L. Ed. 899; Cameron Septic Tank Co. v. Village of Saratoga Springs, 159 F. 453 (C.C.A. 2); Dick v. Lederle Antitoxin Laboratories (D.C.) 43 F.(2d) 628. [6 USPQ 40 (S.D. N.Y. 1930)].

The statement the examiner relied on, "Were the patent for bacteria *per se*, a different situation would be presented," is a trite observation of minimal magnitude as precedent, dealing with a non-issue on which no opinion was expressed. What we find of interest and, indeed, "pertinent" is the fact that the defendant urged the unpatentability of claims because they involved a *life process* of a *living* organism and the court *rejected* the argument. At the outset, the opinion states that one of the defenses was "non-patentable subject matter." The real plaintiff in the case was Commercial Solvents Corporation, exclusive licensee under the Weizmann patent in suit, which corporation was making butyl alcohol and acetone by the Weizmann bacteriological fermentation process, and, with its predecessors, had been doing so since 1918. In 1929 the production was 107,500,000

pounds. The trial court noted that "The record shows that an important and extensive new industry has now been developed and established upon the Weizmann process." It was very clear to the court that it was dealing with a *life process* for, in describing the invention, it said, "'Fermentation' is the chemical change, or the decomposition into new chemical compounds, of a substratum, by living organisms, such, for example, as yeast or bacteria." On the issue whether a *process* dependent upon living organisms and their life processes was patentable subject matter, the court had no doubts. In the last case cited in the above quotation, *Dick v. Lederle*, two years earlier the court had found a scarlet fever toxin and antitoxin and process of making the same to be patentable subject matter notwithstanding the employment of life processes in their preparation. On appeal in the *Guaranty Trust* case, the Third Circuit Court of Appeals affirmed per curiam on the opinion of the trial judge, commenting, *inter alia*, that it had been persuaded "that the invention disclosed in the patent created a new and important commercial enterprise * * *."

These decisions illustrate what we believe to have been the state of the law ever since, namely, that *processes*, one of the categories of patentable subject matter specified in § 101, are uniformly and consistently considered to be statutory subject matter notwithstanding the employment therein of living organisms and their life processes. Witness the action of the PTO in the present case in allowing the

process claims. Other examples of such patentable process claims involving living bacteria are to be seen in the bacterial sewage treatment cases of which one is *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 21 USPQ 69 (CA 7 1934). (See quoted claims 8 and 10 of reissue patent No. 15,140 in fn. 4.) A still earlier one is the *Cameron Septic Tank Co.* case cited in *Guaranty Trust* and decided by the Second Circuit Court of Appeals in 1908, wherein the trial court was reversed and bacterial-action process claims were held valid and infringed. (The original "septic tank.") It seems illogical to us to insist that the existence of life in a manufacture or composition of matter in the form of a biologically pure culture of a microorganism removes it from the category of subject matter which can be patented while the functioning of a living organism and the utilization of its life functions in processes does not effect their status under § 101. Of course it is clear, as the dissenting board member noted, that there is nothing in the words of § 101 which excludes patents for living organisms.

We cannot agree with the board majority's view that § 101 "must be strictly construed." But even a "strict construction," whatever that may entail, fails to lead inexorably to the exclusion of a manufacture or composition of matter because it is alive. The statute makes no distinction between manufactures and compositions on the one hand and processes on the other. If the board is right in excluding products because there is life in them, then logic dictates that

it should take the same position with regard to processes. But it does not do so. Indeed, in light of what the courts have done over the past seventy years in holding such process claims valid, it could not properly do so. We have never heard of a case holding that the categories of patentable subject matter, as enumerated in § 101 or any of its predecessor statutes, should be strictly construed and the board has cited none.

In 1932, when the Board of Appeals was faced with an examiner's contention that a biological process for producing butyl and isopropyl alcohols by bacterial action was unpatentable because the bacteria were doing only what by nature they are capable of doing, its response was that *if such a view were accepted, it would hardly be possible to grant a patent on any chemical process*, indicating an early appreciation of the essential similarity of what we normally think of as "chemical reactions" and the complex *chemical* procedures wrought by the *life* processes of microorganisms. *Ex parte Prescott*, 19 USPQ 178 (1932). As a result of that decision, according to the report of the case, patent No. 1,933,683 was issued Nov. 7, 1933, for "Production of Butyl and Isopropyl Alcohols" with process claims. The board said (19 USPQ at 180):

We are unable to agree with the Examiner that processes involving bacterial action do not involve patentable subject matter * * *.

What we have before us is an industrial product used in an industrial process—a useful or techno-

logical art if there ever was one. See *In re Waldbaum*, 59 CCPA 940, 457 F.2d 997, 173 USPQ 430 (1972). The nature and commercial uses of biologically pure cultures of microorganisms like the one defined in claim 5 are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses. According to an article cited but not relied on by the solicitor entitled "Microbiological Applications and Patents" by Harvey W. Edelblute in *The Encyclopedia of Patent Practice and Invention Management* at 567, edited by R. Calvert (1964), microbiological processes have long been used "to make beer, wine, cheese, bread, pickles and sauerkraut, rett flax, age tobacco, bate leather, produce silage and digest sewage." But more to the point here, in recent years, according to Edelblute, they have come to be used to "produce a vast variety of chemicals and drugs such as alcohols, ketones, fatty acids, amino acids, vitamins, antibiotics, steroids, and enzymes." Edelblute provides a "far from complete list" of chemical reactions carried out by microorganisms, which he names, which include oxidation, reduction, condensation, esterification, amination, deamination, phosphorylation, hydrolysis, decarboxylation, methylation, dismutation, acylation, and dehydration.² In short, microorganisms have come to be important tools in the chemical industry, especially

² "Bacteria are universal biochemists * * *." A. Bryan, C. A. Bryan, & C. G. Bryan, *Bacteriology* v (6th ed. 1962).

the pharmaceutical branch thereof, and when a new and useful tangible industrial tool is invented which is unobvious, so that it complies with the prerequisites to patentability other than the enumerated statutory categories, we do not see any reason to deprive it or its creator or owner of the protection and advantages of the patent system by excluding it from the § 101 categories of patentable invention on the sole ground that it is alive. It is because it is alive that it is useful. The law unhesitatingly grants patent protection to new, useful, and unobvious chemical compounds and compositions, in which category are to be found the *products* of microbiological processes, for example, vitamin B-12 and adrenalin, referred to in note 1 above, and countless other pharmaceuticals. We see no sound reason to refuse patent protection to the microorganisms themselves—a kind of tool used by chemists and chemical manufacturers in much the same way as they use chemical elements, compounds, and compositions which are not considered to be alive, notwithstanding their capacities to react and to promote reaction to produce new compounds and compositions by chemical processes in much the same way as do microorganisms. We think it is in the public interest to include microorganisms within the terms "manufacture" and "composition of matter" in § 101. In short, we think the fact that microorganisms, as distinguished from chemical compounds, are alive is a distinction without legal significance and that disposes of the board's ground of

rejection and the sole reason for refusal of a patent argued by the solicitor.

As for the board's fears that our holding will of necessity, or "logically," make all new, useful, and unobvious species of plants, animals, and insects created by man patentable, we think the fear is far-fetched. In any case, that question is not before us, as we have indicated above. Nor are we influenced by the legislative history of the Plant Patent Act of 1930 in the course of which nobody had anything to say about patent protection for microorganisms, so far as we know. The collective mind of Congress was not turned in that direction. We are not here concerned with interpretation of the Plant Patent Act as this court was in *In re Arzberger*, supra, which simply held that *that act* did not encompass bacteria.

The decision of the board affirming the rejection of claim 5 is *reversed*.

REVERSED

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

Patent Appeal No. 76-712

IN THE MATTER OF THE APPLICATION

OF

MALCOLM E. BERGY, JOHN H. COATS,
AND VEDPAL S. MALIK

Serial No. 477,766

KASHIWA, Judge,* concurring.

I agree with the result and the reasoning of the opinion by Judge Rich joined by Chief Judge Markey. Nevertheless, I wish to emphasize, out of a superabundance of caution, that I read the majority opinion as setting forth an extremely limited holding. While the PTO and the dissenting opinion raise the specter of patenting higher forms of living organisms, quite clearly the majority opinion does not support such a broad proposition. Each case must necessarily be considered on its own facts. On the facts of this case, I join the narrow confines of the majority opinion.

* Judge of the United States Court of Claims sitting by designation pursuant to 28 USC 293(a).

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

Patent Appeal No. 76-712

IN THE MATTER OF THE APPLICATION

OF

MALCOLM E. BERGY, JOHN H. COATS,
AND VEDPAL S. MALIK

Serial No. 477,766

MILLER, Judge, dissenting, with whom BALDWIN,
J., joins.

I do not agree that a biologically pure culture of microorganisms is within the scope of 35 USC 101 intended by Congress.

The board majority concluded—

[35 USC 101] does not specifically proscribe patents on plants, yet it was found necessary to enact a special section in order to reward horticulturalists and agriculturalists (35 U.S.C., Chapter 15, Sections 161-164). *If 35 U.S.C. 101 were to be broadly construed there would clearly not have been any necessity for Chapter 15 of 35 U.S.C.*

We are especially impressed by the legislative history of R.S. 4886 (U.S.C. Title 35, Section 31), the predecessor of the present Chapter 15 of 35 U.S.C.

We believe that the legislative history reveals a clear Congressional intent that plants were not covered by the predecessor of 35 U.S.C. 101.

...

Based upon the legislative history . . . we do not believe that the terms "manufacture" or "composition of matter," as employed in 35 U.S.C. 101, were intended to encompass any living organism, whether plants or the microorganism appellants are claiming here. [Emphasis added.]

The response of the majority opinion here is simply:

Nor are we influenced by the legislative history of the Plant Patent Act of 1930 [ch. 312, 46 Stat. 376] in the course of which nobody had anything to say about patent protection for microorganisms

It then attempts to distinguish between microorganisms and more-complex living things, such as those included within the common means of "plants," saying:

The nature and commercial uses of biologically pure cultures of microorganisms like the one defined in claim 5 are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses.

Such a distinction is purely gratuitous and clearly erroneous. The nature of organisms, whether microorganisms, plants, or other living things, is fundamentally different from that of inanimate chemical compositions. For example, both the microorganisms

claimed herein and honeybees are alive, reproduce, and act upon other materials to form technologically useful products (lincomycin and honey, respectively). This cannot be said of chemical compositions. The weakness of the majority's position is further apparent from its failure to advance any rationale for distinguishing between different types of living things—particularly between a biologically pure culture of a microorganism and plants—for purposes of 35 USC 101.

I agree with the board majority that 35 USC 161, *et seq.*, whose original precursor was the Plant Protection Act of 1930 (1930 Act), and the legislative history of the 1930 Act support the conclusion that living organisms (*e.g.*, plants and biologically pure cultures of microorganisms) were not intended by Congress to be within the scope of 35 USC 101.

That Congress believed it necessary to enact a statute *extending* patent protection to certain plants (see *In re LeGrice*, 49 CCPA 1124, 1139, 301 F. 2d 929, 939, 133 USPQ 365, 374 (1962)) and to continue this protection in a *separate* provision of the present law demonstrates that Congress never intended that plants or other organisms be within the scope of the terms “manufacture” and composition of matter.” If, indeed, organisms were within the scope of such terms, the 1930 Act would have been superfluous. Presumably the 1930 Act was not superfluous, and the majority opinion here contains nothing to rebut that presumption. See *Platt v. Union Pacific Railroad*, 99 U.S. 48, 58 (1878); *In re*

Finch, 535 F.2d 70, 71, 190 USPQ 64, 65 (CCPA 1976); *Skovgaard v. The M/V Tungus*, 252 F.2d 14, 17 (CA 3 1957), *aff'd* 358 U.S. 588 (1959); *United States v. Korpan*, 237 F.2d 676, 680 (CA 7 1956), *rev'd on other grounds*, 354 U.S. 271 (1957); *United States v. C.J. Tower & Sons*, 44 CCPA 1, 5, C.A.D. 626 (1956).

Moreover, the Senate committee report accompanying the bill which became the Plant Patent Act of 1930 (S. Rep. No. 315, 71st Cong., 2d Sess. (1930)) stated:

The purpose of the bill is to afford agriculture, so far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry The bill will remove the existing discrimination between plant developers and industrial inventors. [*Id.* at 1.]

This underscores Congressional understanding that plants were not patentable subject matter under the law then in effect, since, if they were, agriculture would already have been afforded “the same opportunity to participate in the benefits of the patent system.” See *Bobsee Corp. v. United States*, 411 F.2d 231, 237 n.18 (CA 5 1969).

If, prior to the 1930 Act, plants had been within the scope of the patent statutes, as the majority opinion apparently assumes, a plant patent would have had to comply fully with what is now 35 USC 112; but after the 1930 Act, a plant patent for certain plants need not do so (since a plant patent could not be declared invalid if its description “is made as com-

plete as is reasonably possible"—see section 2 of the Plant Protection Act of 1930, 46 Stat. 376). This would have constituted a repeal of the full-compliance requirement in the case of such plants without any Congressional discussion thereof. Repeal by implication is not favored statutory construction. *FTC v. A.P.W. Paper Co.*, 328 U.S. 193, 202, 69 USPQ 215, 219 (1946). The conclusion follows that, prior to the 1930 Act, plants were not within the scope of the patent statutes.

The Plant Variety Protection Act, 7 USC 2321 *et seq.*, although enacted long after the original use of the terms "manufacture" and "composition of matter" appearing in 35 USC 101, further supports the conclusion that Congress did not intend organisms to be included within the scope of such terms. Both the Senate Judiciary Committee report (S. Rep. No. 91-1246, 91st Cong., 2d Sess. 3 (1970)) and the House Committee on Agriculture report (H.R. Rep. No. 91-1605, 91st Cong., 2d Sess. 1 (1970)) accompanying the bill (S. 3070) which became the Plant Variety Protection Act stated:¹

Under patent law, protection is presently *limited* to those varieties of plants which reproduce asexually, that is, by such methods as grafting or

¹ The bill was also reported on by the Senate Committee on Agriculture and Forestry (S. Rep. No. 91-1138, 91st Cong., 2d Sess. (1970)), which included a letter from the Under Secretary of Agriculture stating that the proposed legislation would provide the "incentive for private enterprise to undertake the research and development required to produce novel varieties of sexually produced plants."

budding. No protection is available to those varieties of plants which reproduce sexually, that is, generally by seeds. Thus, patent protection is *not* available with respect to new varieties of most of the economically important agricultural crops, such as cotton or soybeans. [Emphasis added.]

Thus, the Patent Act of 1952 was considered to be limited to plants falling under 35 USC 161, and 35 USC 101 was not considered to cover any plants whatsoever.

The majority, in holding that the biologically pure culture of a microorganism defined by claim 5 constitutes patentable subject matter, relies heavily on the fact that processes of *using* the microorganism constitute patentable subject matter, saying:

It seems illogical to us to insist that the existence of life in a manufacture or composition of matter in the form of a biologically pure culture of a microorganism removes it from the category of subject matter which can be patented while the functioning of a living organism and the utilization of its life functions in processes does not affect their status under § 101.

However, this court has pointed out that claims directed to processes of using an algorithm to *operate* a system constitute patentable subject matter while claims directed to the algorithm *per se* (or to methods of *calculating* using the algorithm) do not. See *In re Waldbaum*, 559 F.2d 611, 616, 194 USPQ 465, 470 (Cust. Ct. & Pat. App. 1977) (*Waldbaum II*). Compare *In re Richman*, 563 F.2d 1027, 1028 (Cust. Ct.

& Pat. App. 1977) with *In re Flook*, 559 F.2d 21 (Cust. Ct. & Pat. App. 1977). Similarly here, the fact that claims directed to a process of using microorganisms constitute patentable subject matter does no logically compel the conclusion that claims to biologically pure cultures of microorganisms are patentable.²

Moreover, by emphasizing the microorganism portion of a claim to the process of using the microorganism, the majority opinion is taking an approach rejected by this court in cases such as *In re Chatfield*, 545 F.2d 152, 158, 191 USPQ 730, 736 (CCPA 1976), *cert. denied*, 46 U.S.L.W. 3203 (October 4, 1977), and *In re Deutsch*, 553 F.2d 689, 691 n.3, 193 USPQ 645, 647 n.3 (Cust. Ct. & Pat. App. 1977), namely dissecting the claim and concentrating on one portion of the claim in determining the issue of patentable subject matter.

The majority opinion says "it is in the public interest to include microorganisms within the terms

² The majority also says that the claimed culture "is an industrial product used in an industrial process—a useful or technological art if there ever was one. See *In re Waldbaum*, 59 CCPA 940, 457 F.2d 997, 173 USPQ 430 (1972) [*Waldbaum I*]." However, the question is not whether the claimed culture is in a technological art, but whether the claimed subject matter was intended by Congress to be within the scope of 35 USC 101. Cf. *Gottschalk v. Benson*, 409 U.S. 63, 175 USPQ 673 (1972). Further, it is to be noted that claims in the Waldbaum application were rejected by the PTO after this court's decision in *Waldbaum I*, *supra*, based on the Supreme Court's reasoning in *Benson*, which rejection was affirmed by this court in *Waldbaum II*, *supra*.

'manufacture' and 'composition of matter' in § 101." Although such a statement might be of interest to an appropriate committee of Congress, it has no relevance to the court's responsibility for determining Congressional intent. As noted by Chief Judge Markey in his concurring opinion in *In re McKellin*, 529 F.2d 1324, 1333, 188 USPQ 428, 437 (Cust. Ct. & Pat. App. 1976):

[T]he patent law is statutory. Our representative form of government requires that the enactments of its Congress must always be, at the very least, the starting point. There being no common law of patents, we should take care to fill the Holmesian interstices of the statute with judge-made law only under the gravest and most impelling circumstances.

The majority opinion, after stating that "[w]e consider the product-of-nature issue . . . no longer in the case," then finds the issue "wholly lacking in merit." Since the culture defined in claim 5 is not a "manufacture" or a "composition of matter" and since we do not have the view of the board majority on the product-of-nature issue, I would not reach that issue on this appeal.

In view of the foregoing, the decision of the board should be affirmed.

30a

APPENDIX B

UNITED STATES COURT OF CUSTOMS
AND PATENT APPEALS

MANDATE

No. 76-712

IN THE MATTER OF THE APPLICATION OF
MALCOLM E. BERGY, JOHN H. COATS AND
VEDPAL S. MALIK

Serial No. 477,766

ON APPEAL FROM THE BOARD OF APPEALS

This CAUSE having been heard and considered,
it is

ORDERED AND ADJUDGED: Reversed

DATED October 6, 1977

Petition for rehearing denied, November 23, 1977.
Judge Baldwin and Judge Miller would grant the
petition.

A True Copy

TEST:

George E. Hutchinson,
Clerk,
United States Court of
Customs and Patent
Appeals

Certified this 30th day of
November 1977

By /s/ George E. Hutchinson

31a

APPENDIX C

PATENT APPEAL NO. 76-712

OPINION AND DECISION OF BOARD OF APPEALS,
JUNE 22, 1976

Before MILESTONE and BLECH, *Examiners-in-Chief*,
and KATZ, *Acting Examiner-in-Chief*.

BLECH, *Examiner-in-Chief*.

This is an appeal from the final rejection of claim
5. Claims 1-4, the only other claims in the case, stand
allowed.

The appealed claim is:

5. A biologically pure culture of the micro-
organism *Streptomyces vellosus*, having the iden-
tifying characteristics of NRRL 8037, said cul-
ture being capable of producing the antibiotic
lincomycin in a recoverable quantity upon fer-
mentation in an aqueous nutrient medium con-
taining assimilable sources of carbon, nitrogen
and inorganic substances.

The claimed invention relates to a biologically pure
culture of a specific microorganism. The micro-
organism is capable of producing the antibiotic lin-
comycin.

No references have been applied against the ap-
pealed claim, the sole rejection being under 35 U.S.C.
101 in that it is drawn to non-statutory subject
matter.

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

It is the Examiner's position that the appealed claim defining a microorganism does not fall under any of the categories listed in Section 101 of Code 35 and, consequently, no patent can be granted thereon.

We have extensively researched prior court decisions for guidance to the question of whether or not a microorganism, being a living thing, is or is not within the realm of statutory patentable subject matter, but, other than possible non-controlling dicta, have not found any case directly in point.

It is our view that 35 U.S.C. 101 must be strictly construed and, when so interpreted, precludes the patenting of a living organism. We reach this conclusion on the basis that only those categories of subject matter specifically enumerated in the statute are patentable and a living organism does not fall within the scope of any of the categories listed. An analogous result has been reached by the courts with respect to nonpatentability of mental processes, printed matter or methods of doing business none of which are also expressly excluded by the indicated section of the statute, but neither can they be said or have been held to be included thereby.

Further, and even more significantly, this section of the statute does not specifically proscribe patents on plants, yet it was found necessary to enact a special section in order to reward horticulturists and agriculturalists (35 U.S.C., Chapter 15, Sections 161-164). If 35 U.S.C. 101 were to be broadly construed there would clearly not have been any necessity for Chapter 15 of 35 U.S.C.

We are especially impressed by the legislative history of R. S. 4886 (U.S.C. Title 35, Section 31), the predecessor of the present Chapter 15 of 35 U.S.C. We believe that the legislative history reveals a clear Congressional intent that plants were not covered by the predecessor of 35 U.S.C. 101. We quote from the report of the Committee on Patents, found on page 1319 of *In re Arzberger*, 27 CCPA 1315, 112 F.2d 834, 1940 C.D. 653, 521 O.G. 272, 46 USPQ 32:

"The bill will remove the existing discrimination between plant developers and industrial inventors,"

and further

"No one has advanced a just and logical reason why reward for service to the public should be extended to the inventor of a mechanical toy and denied to the genius whose patience, foresight, and effort have given a valuable new variety of *fruit or other plant* to mankind."

Based upon the legislative history as discussed in *Arzberger, supra*, we do not believe that the terms

"manufacture" or "composition of matter," as employed at 35 U.S.C. 101, were intended to encompass any living organisms, whether plants or the microorganism appellants are claiming here.

If we were to adopt a liberal interpretation of 35 U.S.C. 101 new types of insects, such as honeybees, or new varieties of animals produced by selective breeding and cross-breeding would be patentable. Moreover, those plants which are excluded from the scope of 35 U.S.C. 161, such as tuber propagated plants or plants which can be reproduced only sexually, would be patentable under 35 U.S.C. 101. We do not believe that Congress intended 35 U.S.C. 101 to encompass any living organisms, whether they be plants or microorganisms.

Taking the position that living organisms are non-statutory subject matter under 35 U.S.C. 101 we do not reach and need not decide whether patenting of the claimed microorganism is precluded due to it being a "product of nature." The affidavits under Rule 132 present in the case are thus not germane to the issue which we consider is presented to us by the facts of this case.

The decision of the Examiner is affirmed.

AFFIRMED

BOARD OF APPEALS

/s/ G. K. Milestone
G. K. MILESTONE
Examiner-in-Chief

/s/ Blech
Examiner-in-Chief

KATZ, *Acting Examiner-in-Chief, dissenting:*

The majority bases its opinion strictly on the viewpoint that the terms "composition" and "manufacture," as employed in 35 U.S.C. 101, were not intended to encompass living organisms.

I consider that the bacteria culture claimed falls either into the category of "composition" or "manufacture" if steps were necessary to treat the bacteria to obtain the defined culture.

Appellants and the Examiner have relied on the following cases:

Guaranty Trust Co. of New York v. Union Solvents Corp., 54 F.2d 400, 12 USPQ 47;

In re Mancy et al., 499 F.2d 1289, 182 USPQ 303;

Merck & Co., Inc. v. Chase Chemical Company et al., 273 F. Supp. 68 (D. N.J. 1967), 155 USPQ 139;

Merck & Co., Inc. v. Olin Mathieson Chemical Corporation, 253 F.2d 156 (CA 4, 1958), 116 USPQ 484;

Kuehmsted v. Farbenfabriken of Elberfeld Co., 179 Fed. 701 (CA 7, 1910), cert. den. 220 US 662;

Parke-Davis & Co. v. H. K. Mulford Co., 189 Fed. 95 (C.C. S.D. N.Y. 1911), aff'd 196 Fed. 496 (CA 2, 1912);

Ex parte Yale et al., 119 USPQ 256;

Ex parte Hillyer et al., 102 USPQ 126;

Ex parte Parke et al., 64 USPQ 335;

In re Bergstrom et al., 427 F.2d 55, 166 USPQ 256;

In re Williams, 36 CCPA 756, 171 F.2d 319, 80 USPQ 150; and

Funk Brothers Seed Company v. Kalo Inoculant Company, 76 USPQ 280.

In my determination of the issues, I have considered not only those cases, but also:

In re Arzberger, 27 CCPA 1315, 1940 C.D. 653, 112 F.2d 834, 521 O.G. 272, 46 USPQ 32;
Ex parte Grayson, 51 USPQ 413 (PO Bd. of App., 1941);
Armstrong Seatag Corporation v. Smith's Island Oyster Co., 254 Fed. Rep. 821;
Armour Pharmaceutical Co. v. Richardson-Merrell, Inc., 396 F.2d 70, 158 USPQ 9;
Kalo Inoculant Company v. Funk Brothers Seed Company, 161 F.2d 981, 74 USPQ 1; and
In re Davis et al., 49 CCPA 1196, 305 F.2d 501, 134 USPQ 256.

The Wegner article has also been studied:

Wegner, "Patent Protection for Microorganisms," *International Review of Industrial Property and Copyright Law*, ICC, Vol. 5, No. 3 (1974), pages 285-291.

None of the cases deal directly with the question of whether microorganism cultures fall within the statutory category of what may properly be patented, although a number of cases touch on the subject and may give guidance.

The Examiner has stressed the Guaranty Trust Co., *In re* Mancy et al, and Funk Brothers cases.

In the penultimate paragraph of the Guaranty Trust Co. decision, the Court comments that

"were the patent for bacteria *per se* a different situation would be presented."

The patent referred to is drawn to the manufacture of acetone and butyl alcohol by a fermentation process employing a certain strain of bacteria. The Court's ruling, however, does not indicate what the holding would be if the bacteria, *per se*, were to be claimed.

In the Mancy et al. case, all claims on appeal were drawn to a process. However, the CCPA expressed the following dictum:

"Here appellants not only have no allowed claim to the novel strain of *Streptomyces* used in their process but would, we presume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a 'product of nature'."

Both the Examiner and appellants appear to be under the impression that the CCPA is inferring that new strains are products of nature and, accordingly, non-statutory.

I do not so interpret the Court's statement. The CCPA appears to indicate that while there is no art showing the strain, the strain, in actuality, is not novel since it exists in nature. It would then follow that the discovery, or isolation, of such strain does not make it new. Accordingly, the claim would not be obtained because it was to known subject matter, rather than on the basis that the subject matter was non-statutory.

The District Court's ruling, as described in the Court of Appeals decision in the Kalo Inoculant Com-

pany case, indicates that the District Court believed that the patentee's work "could not be classified under any subject matter defined as patentable by the Congressional Act."

However, of major interest is that in the appellate decisions, both the Circuit Court of Appeals (*Kalo Inoculant v. Funk Brothers*) and the Supreme Court (*Funk Brothers v. Kalo Inoculant*) strongly imply that mixtures of organisms, *per se*, are proper subject matter for which patents may be granted.

The majority of the U.S. Supreme Court, in the *Funk Brothers* case, did not conclude that bacteria mixtures are improper patent subject matter, and thus did not close out the controversy. Instead, they based their decision on the determination of patentability of the mixtures and found the claims invalid for want of invention.

In the *Funk Brothers* case, patentee discovered that certain strains of bacteria could be mixed and used to inoculate a number of different types of nitrogen-fixing plants. Prior to this discovery, it was necessary to use a specific bacteria strain for each type of plant since mixtures of strains were unsuitable, the different strains inhibiting each other.

The Court held that the composite culture was new and useful, but still not patentable since no species of bacteria in the mix acquired a different use, the combination did not produce a new bacteria, or a change in the six species of bacteria, and no enlargement of the range of utility since each species had the same effect it always had and the bacteria performed

in their normal way. It was the Court's opinion that the discovery of the non-inhibiting action of certain strains of bacteria was merely a discovery of a hitherto unknown, but existing phenomenon of nature, which may not be monopolized.

Mr. Justice Frankfurter, in his concurring opinion, agreed with the Circuit Court of Appeals, and stated:

"Insofar as the court below concluded that the packaging of a *particular mixture of compatible strains is an invention and as such patentable*, I agree, provided not only that a new and useful property results from their combination, but also that the particular strains are identifiable and adequately identified." (underlining added)

Justice Frankfurter concluded, however, that the patentee had not properly identified the strains and thus was not entitled to a patent.

Mr. Justice Burton and Mr. Justice Jackson, in dissenting, stated:

"When the patentee discovered the existence of certain strains of bacteria which, when combined with certain other strains of bacteria, would infect two or more leguminous plants without loss of their respective nitrogen-fixing efficiencies, and utilized this discovery by segregating some of these mutually non-inhibitive strains and combining such strains into composite inoculants, *we agree with MR. JUSTICE FRANKFURTER that the combinations so produced satisfied the statutory requirements of invention or discovery. . .* These products were a prompt and substantial

commercial success, filling a long-sought and important agricultural need." (underlining added)

The dissenting Justices took the position that the invention was properly defined and thus patentable. Of major interest, however, is that they made it clear that they considered the subject matter itself to be statutory.

The majority opinion in Funk Brothers specifically ruled on the patentability of the mixture of organisms when compared to what was known in the art and what was present in nature, and did not deal directly with whether the subject matter itself is statutory. However, it appears reasonable that the Court must have dealt with the same first hurdle we have before us. Is the bacteria culture itself statutory? The Court seems to have acted on the assumption that the subject matter of the controversy was, like any other subject matter, not to be evaluated for patentability in the ordinary manner. At the very least, the majority holding can be said to be neutral on the subject of whether strains of bacteria fall within the statutory classes of patentable subject matter.

However, I am strongly influenced by the positive and definitive language in the concurring and dissenting opinions. Both opinions state that the combination of bacteria cultures satisfy the statutory requirements. Neither opinion conflicts with the majority opinion in this regard.

Appellants have brought to the Board's attention patents which claim a composition of matter com-

prising spores of a certain bacteria in a carrier. Note U.S. Patents 3,632,747, 3,642,982 and 3,651,215. Patent 3,642,982 specifically claims a composition of living bacteria in an inert carrier, which may be a culture medium (claim 2). Such patents are not precedent, but they are of interest.

It is true that the courts have decided that certain categories of subject matter (mental processes, printed matter, methods of doing business) do not fall within the boundaries of Section 101, and that it was found necessary to enact a separate statute to provide protection to those who developed or discovered new plant varieties. However, this does not logically lead to a conclusion that Section 101 was not intended to provide patent protection for living organisms.

Of the various acknowledged non-statutory categories, plants are most akin to the living organisms. Both materials are alive. However, that is where the similarity stops. As held in the *Arzberger* case, living organisms (bacteria) are not plants within the meaning of the plant statute. While bacteria may possess some of the characteristics of plants, the word "plant" is used in its popular sense and not in its scientific sense since the statute was designed for the benefit of agriculturists. Thus, the exclusion of plants from 35 U.S.C. does not necessarily apply to bacteria.

Further, I do not believe that the fact that plants and bacteria have some properties in common is sufficient basis for holding that bacteria are to be excluded from patent coverage. Such line of reasoning would, for example, preclude the patenting of plant-

derived cellulosic materials, merely on the basis that plants also contain cellulose.

Since I do not find it improper to claim living organisms, I would make no distinction between a single living organism, or such organism mixed with other organisms or with non-living materials, such as carriers or culture mediums.

In view of the discussed cases, and since 35 U.S.C. 101 does not expressly exclude patents to living organisms, it is my opinion that living organisms, as claimed, may be patented if such claims also fulfill the other requirements of the statute.

I would determine whether the claimed culture is new or unobvious, as required by the statute.

Appellants urge that claim 5 is not directed to a product of nature, but rather to a biologically pure culture obtained by the work of a microbiologist. It is their view that clearly patentable subject matter is defined. Three affidavits have been submitted by appellants and, the uncontested evidence is that the biologically pure culture of claim 5 is not found in nature, that the type of microbe (actinomycetes), to which the microorganism belongs, makes up a portion of the microbes found in certain sample of earth, that the microorganisms found in soil are complex in kind and metabolic activities and that a biologically pure culture must be produced before a microorganism can be taxonomically characterized, and, further, that the impure culture will not give the desired fermentation product.

The majority decision does not find sufficient reason to decide whether patenting of the claimed microorganism is precluded due to it being a "product of nature." However, because the Examiner has, in part, based his rejection on this theory, and since I do not agree that the claim is properly rejected solely because it is drawn to a living organism, I will go into this aspect.

The expression "product of nature" does not appear in Section 101 and, as such, a material should not be excluded on that basis alone, as being non-statutory. Rather, I view a "product of nature" as being something that "exists" in nature and therefore evidence that it may not be "new" as this expression finds meaning in the Patent Statute. Accordingly, I would treat "products of nature" like any other material and determine whether they are new or obvious in view of the state of the art.

Certainly vitamin B-12, as it exists in liver, and adrenalin, as it appears in adrenal glands, are products of nature, yet the courts have held (Merck & Co., B-12 and Parke Davis and Co., adrenalin) that when such materials are extracted and concentrated in a purified form they are patentable. Accordingly, it is not sufficient to determine whether the pure culture claimed is a product of nature. For a proper evaluation from the patentability aspect, such culture must be examined and evaluated on the basis of whether it meets the novelty and/or unobviousness requirements set forth in the statute.

I am tempted to give my view on the patentability of the pure culture of the defined organism. However, this issue has not been raised in this case. Before deciding, it would be appropriate to have the benefit of appellants' and the Examiner's viewpoints. Therefore, I would remand for a fuller consideration of this aspect.

BOARD OF APPEALS

/s/ Murray Katz
MURRAY KATZ
Examiner-in-Chief
(Acting)

APPENDIX D

PATENT APPEAL NO. 76-712

LETTER OF EXAMINER, FEBRUARY 6, 1975

- ☒ This application has been examined.
- ☒ Responsive to communication filed 1/27/75.
- ☒ This action is *made final*.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS LETTER.

* * * *

PART II

Summary of Action

1. ☒ Claims 1-5 are presented for examination.
2. ☒ Claims 1-4 are allowed.

* * * *

4. ☒ Claim 5 is rejected.

* * * *

Claim 5 is rejected under 35 USC 101 as nonstatutory subject matter. Claim 5 claims a product of nature (*Streptomyces vellosus* NRRL 8037). See *In re Mancy et al.* 182 USPQ 303 at page 306, second sentence before [4].

Claims 1-4 are allowable in view of the declaration filed January 27, 1975.

This action is made FINAL.

/s/ A. Louis Monacell
A. LOUIS MONACELL
Examiner
Group Art Unit 172

LETTER OF EXAMINER, MARCH 11, 1975

☒ THE PERIOD FOR RESPONSE IS EXTENDED TO RUN 4 MONTHS FROM THE DATE OF THE FINAL REJECTION. 855 O.G. 1109.

☒ Appellant's Brief is due in accordance with Rule 192(a).

Appellant's response to the final rejection, filed 2/20/75, has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

* * * *

4. ☒ The affidavit, exhibit or request for reconsideration has been entered but does not overcome the rejection.

* * * *

/s/ A. Louis Monacell
A. LOUIS MONACELL
Examiner
Group Art Unit 172